

Appl. No.: 10/659,475 .

Group Art Unit: 1617

Applicants' Reply to the Office Action mailed October 6, 2004

### REMARKS

Claims 1 and 3-16 are currently pending in the instant application.

Claims 1 and 16 have been amended to specify that the medium-chain triglyceride is derived from the esterification of a substantially pure fatty acid and substantially pure glycerol. Support for these amendments can be found in original claim 2, which has been canceled herein, and in the Specification, for example, at page 5, lines 3-11. Claims 3, 4 and 5 have been amended to depend from claim 1. No new matter has been introduced by these amendments. Applicants submit that no fees for additional claims are due. A complete listing of all claims ever presented is included herein in accordance with 37 C.F.R. §1.121(c). Entry of the amendments is therefore proper and respectfully requested.

In the Office Action, the Examiner rejects claims 1-5, 14 and 15 under 35 U.S.C. §102(e), as being anticipated by U.S. Pat. No. 5,780,056 of Akamatsu, *et al.* (hereinafter referred to as "Akamatsu"), as evidenced by U.S. Pat. No. 5,004,756 of Ogawa, *et al.* (hereinafter referred to as "Ogawa"). Specifically, the Examiner contends that Akamatsu discloses a carotenoid composition containing lycopene suspended in a medium chain triglyceride, which may also comprise an antioxidant in amounts of from 0.01 to 15% by weight. The Examiner also contends that Ogawa serves as evidence that medium chain triglycerides of fatty acids having 8 to 12 carbons atoms were known and commonly abbreviated "MCT". The Examiner further argues that the product-by-process clause of claim 2 is of no patentable weight because the claim is drawn to the composition, not the process employed to produce it. Applicants respectfully traverse the Examiner's rejection and the arguments and contentions in support thereof for the following reasons.

Applicants' claimed invention, as amended herein, is directed to carotenoid compositions comprising lycopene suspended or dispersed in a medium-chain triglyceride, *wherein the medium-chain triglyceride is derived from esterification of a substantially pure medium chain fatty acid and substantially pure glycerol*. As set forth in the Specification, the use of medium chain triglycerides derived from the esterification of substantially pure glycerol and fatty acids, rather than natural source oils extracted with solvents, reduces the presence of

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impurities that may cause or induce oxidation of the carotenoid. (*See*, Applicants' Specification, p. 3, lines 14-18, and p. 5, lines 3-11).

Applicants' respectfully submit that the claimed carotenoid compositions are different from the prior art, in part, because of the claimed process used to produce them. The use of medium chain triglycerides prepared via esterification of substantially pure glycerol and substantially pure fatty acids, results in carotenoid compositions which are more resistant to oxidation. As can be seen from Example 1, which begins at line 15, page 9 of the Specification, the long term stability of a carotenoid composition containing a medium chain triglyceride prepared by esterifying fractionally distilled fatty acids and highly pure glycerol is far superior to a carotenoid suspended in soya bean oil. (*See*, Applicants' Spec., Table 1 at p. 12). More specifically, the carotenoid composition according to a preferred embodiment of the present invention contains the same amount of lycopene after three months, whereas the carotenoid composition prepared using soya bean oil contains almost half of the original lycopene content. (*See, id.*). For the sake of clarity, it is emphasized that "substantially pure" with respect to the fatty acid does not imply that the acid reactant must be a single fatty acid. For example, a fractionally distilled blend of predominantly C<sub>8</sub> and C<sub>10</sub> fatty acids can certainly be substantially pure and is well within the scope of the presently claimed invention.

Akamatsu fails to teach a carotenoid composition containing lycopene dispersed or suspended in a medium chain triglyceride prepared by esterifying substantially pure glycerol and substantially pure fatty acids. Accordingly, Akamatsu fails to anticipate the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

In the Office Action, the Examiner rejects claims 6-13 and 16 under 35 U.S.C. §103(a), as being unpatentable over Akamatsu. Applicants respectfully traverse the Examiner's rejection and the arguments and contentions in support thereof for the following reasons.

As discussed above, Akamatsu fails to teach Applicants' claimed invention which is directed to carotenoid compositions containing lycopene dispersed or suspended in a medium chain triglyceride prepared by esterifying substantially pure glycerol and a substantially pure fatty acid or acids. Moreover, Akamatsu fails to suggest the use of such medium chain

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triglycerides. Nowhere in Akamatsu is the esterification of substantially pure glycerol and substantially pure fatty acids mentioned. One of ordinary skill in the art would find no teaching or suggestion in the disclosure of Akamatsu which would motivate a modification of the teachings of Akamatsu to use such substantially pure reactants in the formation of a medium chain triglyceride.

Accordingly, Applicants submit that Akamatsu fails to establish a *prima facie* case of obviousness. Reconsideration and withdrawal of this rejection are respectfully requested.

In view of the amendments made herein and the remarks set forth above, Applicants submit that the claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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(Date):

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